Testimony of David B. Ross, M.D., Ph.D.
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Subcommittee on Oversight and Investigations
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Oral Testimony

Good morning, Mr. Chairman and Members of the Committee. Thank you for the opportunity to speak before this committee. I am here today to speak about the drug Ketek.

My name is David Ross. For purposes of identification only, I am currently National Director of Clinical Public Health Programs for the US Department of Veterans Affairs; I am here today as a private citizen. I was trained as a medical doctor at New York University and Yale and am board certified in internal medicine and infectious diseases. I take care of patients at my local VA hospital and teach medical students and residents.

I served for ten years at the FDA in positions ranging from a primary medical reviewer of New Drug Applications to a member of the Senior Leadership Team of FDA's Office of New Drugs. I served as both the primary safety reviewer and safety team leader for Ketek.

FDA approved Ketek despite knowing that it could kill people from liver damage and that tens of millions of people would be exposed to it; despite FDA knowing that the drug's maker submitted fabricated data; and despite knowing that Ketek is no better than other antibiotics, and may not even work.

Why does Ketek matter? Because FDA broke its own rules and allowed Ketek on the market; because dozens of patients have died or suffered needlessly; because FDA

allowed Ketek's maker to experiment with it on children over reviewers' protests; because FDA ignored warnings about fraud; and because FDA used data it knew was false to reassure the public about Ketek's safety.

In March 2000, when Ketek was submitted to FDA, reviewers were alarmed over a patient treated with Ketek who had developed severe liver damage, an event that could mean hundreds or thousands of deaths every year. In April 2001, a Federal Advisory Committee was so concerned about Ketek's potential to kill patients that it required a large safety study before the drug could be approved. In October 2002, FDA reviewers examining the safety study found serious and pervasive misconduct pointing at fraud. In December 2002, Ketek's manufacturer admitted that it had known about "issues" at its largest enroller – but hadn't told the FDA. The company claimed that there were no other "issues" with the study – even though every study site inspected by FDA turned out to have major problems, an unprecedented situation. In January 2003 – over reviewers' protests – FDA managers hid the evidence of fraud and misconduct from the Advisory Committee, which was fooled into voting for approval. Starting the same month, FDA managers also pushed to use uncontrolled, unreliable side effect reports from overseas – supplied by the drug's manufacturer without independent checking by FDA – as proof of Ketek's safety, something that had never been done before.

In April 2003, in response to a fraud investigation, the company turned over records the FDA– with most of the text blacked out. FDA managers did nothing.

In July 2003, FDA managers were warned by criminal investigators about possible fraud by the drug company with Ketek. They did nothing.

In October 2003, FDA received records from the company that raised further concerns about fraud – FDA managers didn't even review them.

In March 2004, FDA's own Division of Scientific Investigations concluded that none of the safety study data was reliable. One week later, FDA managers approved Ketek. Although FDA managers publicly deny it, internal correspondence shows that they used the safety study, and repeatedly cited it as evidence of Ketek's safety.

In February 2005 – seven months after Ketek's launch - FDA managers received the first reports of fatal Ketek-related liver failure. They did nothing.

In February 2006, I and other reviewers warned senior FDA managers in writing about the problems with Ketek, including reviewers being pressured to change their opinions. The managers did nothing.

In March 2006, FDA managers received new warnings from criminal investigators. They did nothing.

In May 2006, FDA managers received warnings from safety reviewers that Ketek was much more dangerous than comparable antibiotics. They did nothing.

Only after Congressional subpoenas – which FDA resisted - and stories in the news media about Ketek and fraud, did FDA managers finally do anything – they reworded the label.

In late June of 2006, FDA reviewers, including myself, were summoned to a meeting with Commissioner von Eschenbach, in which he compared the FDA to a foot-ball team, and told reviewers that if they told anyone outside the FDA about the problems

with Ketek, they'd be "traded from the team." Rather than be silenced, I chose to move on to my current position.

How did this happen? The FDA reviewers did their job. This is not their fault. Ketek can be laid directly at the door of senior FDA managers who knew better – because they were told repeatedly by reviewers and criminal investigators – but chose to look the other way. Their behavior was worse than being in a state of denial. FDA managers were so bent on approving Ketek that they suppressed evidence of fraud and pressured reviewers – including myself – to change their reviews.

What's the bottom line? An unsafe drug got past the system despite warning after warning about fraud, liver damage, and death because FDA managers at the highest levels refused to listen.

Will this happen again? Yes. Without significant changes in our drug safety system and in FDA, we are certain to see more Keteks. Thank you. The views presented here are my own. I would be happy to answer any questions.